

### **REMARKS**

This Amendment is responsive to an Office Action in this case mailed on July 2, 2004. In the Office Action, the Examiner objected to the language and format of the Abstract of the disclosure; objected to the disclosure based on informalities; objected to claims 1 and 7 based on informalities; rejected claims 1 and 7 under 35 U.S.C. § 102(b) over European Patent No. EP 0 693 297 A1 to Bellco (hereinafter "Bellco"); rejected claims 1-12 under 35 U.S.C. §102(e) over U.S. Patent No. 6,537,240 to Cavicchioli et al. (hereinafter "Cavicchioli"); rejected claims 1 and 7 under 35 U.S.C. §102(e) over U.S. Patent No. 5,866,015 to Krämer (hereinafter "Krämer"); and rejected claims 2-6 and 8-12 under 35 U.S.C. §102(e), or in the alternative, under 35 U.S.C. §103(a) over Krämer. Applicants respectfully traverse these rejections.

Claims 13-43 are pending in this application. By amendment in this Reply, claims 1-12 are cancelled without prejudice, and claims 13-43 are added to more appropriately claim the present invention. No new subject matter has been added.

In the Office Action, the Examiner objected to the language and format of the Abstract of the disclosure. Accordingly, Applicants submit a replacement Abstract on a separate sheet attached hereto, which complies with 37 C.F.R. § 1.72. Thus, Applicants respectfully request that the Examiner withdraw this objection.

The Examiner objected to the specification for not including headings distinguishing the different sections. While not required, section headings are added by amendment in this Reply. Thus, Applicants respectfully request that the Examiner withdraw this objection.

The Examiner also objected to claims 1 and 7 based on informalities. In this Reply, Applicants cancelled claims 1-12, adding claims 13-43. The informalities causing the Examiner's objections to originally-filed claims 1 and 7 are not present in new claims 13-43. Thus, Applicants respectfully request that the Examiner withdraw this objection.

New claims 13, 19, and 24 recite, among other things, methods for determining blood recirculation. The method in new claim 13 recites "inducing a disturbance in the blood flowing in the return line, said disturbance coming from a succession of increases and decreases of a value of a blood parameter around an average value or around a predetermined profile." The methods in new claims 19 and 24 recite "inducing a succession of variations of a value of a blood parameter in the blood flowing in the return line, each variation having an increase and a decrease of said blood parameter value." Support for these limitations in claims 13, 19, and 24, may be found, for example, on page 8, line 37 – page 9, line 38.

New claims 28, 34, 38, and 42 recite devices for determining blood recirculation. The device in new claim 28 includes a "means for inducing a succession of increases and decreases of a value of a blood parameter around an average value or around a predetermined profile in the blood flowing in the return line." The devices in new claims 34 and 38, include a "means for inducing a succession of variations of a value of a blood parameter in the blood flowing in the return line, each variation comprising an increase and a decrease of said blood parameter value." Support for these limitations in new claims 28, 34, and 38, may be found, for example, on page 9, at lines 11-38. The device in new claim 42 includes "means for causing a succession of changes of

hemoglobin concentration of the blood flowing in the return line.” Support for this limitation in new claim 42, may be found, for example, on page 9, at lines 11-22.

Applicants respectfully traverse the Examiner’s rejection of originally-filed claims 1 and 7 under 35 U.S.C. § 102(b) as being anticipated by Bellco; the Examiner’s rejection of originally-filed claims 1-12 under 35 U.S.C. § 102(e) as being anticipated by Cavicchioli; and the Examiner’s rejection of originally-filed claims 1-12 under 35 U.S.C. § 102(e) as being anticipated by Krämer. In order to properly anticipate Applicants’ claimed invention under 35 U.S.C. § 102, each and every element of the claim in issue must be found, either expressly described or under principles of inherency, in a single prior art reference. Furthermore, “[t]he identical invention must be shown in as complete detail as is contained in the . . . claim.” See M.P.E.P. §2131 (8th ed., Aug. 2001), quoting *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). Finally, “[t]he elements must be arranged as required by the claim.” M.P.E.P. § 2131 (8th ed., 2001), p. 2100-69. Applicants respectfully submit, however, that the Examiner’s rejection is moot in light of Applicants’ cancellation of claims 1-12.

Insofar as the Examiner’s rejections under 35 U.S.C. § 102 are relevant to new claims 13-43, Applicants respectfully submit that new claim 13, for example, is not anticipated by Bellco, Cavicchioli, or Krämer, at least because each of those references fails to teach each and every element of the claim. In particular, Bellco, Cavicchioli, and Krämer each fails to disclose a method comprising “inducing a disturbance in the blood flowing in the return line, said disturbance coming from a succession of increases and decreases of a value of a blood parameter around an average value or around a

predetermined profile,” as recited in new claim 13. Further, Applicants respectfully submit that new claim 28, for example, is not anticipated by Bellco, Cavicchioli, or Krämer, at least because each of those references fails to teach each and every element of the claim. In particular, Bellco, Cavicchioli, and Krämer each fails to disclose a device comprising a “means for inducing a succession of increases and decreases of a value of a blood parameter around an average value or around a predetermined profile in the blood flowing in the return line,” as recited in new claim 28.

Bellco discloses an apparatus, which, on the basis of a set variation in the saline ions in the blood fed along tube 8, and on the basis of a number of findings, provides for determining the amount of purified blood recirculated, and so evaluating the effectiveness of the dialysis treatment. See, e.g., Abstract; col. 1, lines 19-43. Bellco, however, fails to teach the claimed method including a step of “inducing a disturbance in the blood flowing in the return line, said disturbance coming from a succession of increases and decreases of a value of a blood parameter around an average value or around a predetermined profile,” as recited in new claim 13, for example. Nor does Bellco disclose “determining a blood recirculation value in a vascular access of the patient between the return line and the withdrawal line, as a function of said at least first and second acquired values,” relating to at least first and second variations of the blood parameter, as recited in new claim 19, for example.

Cavicchioli discloses a method comprising the step of determining the value of the blood recirculation in an vascular access of a patient whose blood is subjected to treatment in a blood treatment apparatus, which is connected to the patient by an arterial line, interconnecting the vascular access with an inlet of treatment apparatus,

and a venous line, interconnecting an outlet of the treatment apparatus with the vascular access. See, e.g., col. 3, lines 39-47. Cavicchioli, however, also fails to teach “inducing a disturbance in the blood flowing in the return line, said disturbance coming from a succession of increases and decreases of a value of a blood parameter around an average value or around a predetermined profile,” as recited in new claim 13, for example. Nor does Cavicchioli disclose “determining a blood recirculation value in a vascular access of the patient between the return line and the withdrawal line, as a function of said at least first and second acquired values,” relating to at least first and second variations of the blood parameter, as recited in new claim 19, for example.

Krämer discloses a method for operating a hemotherapeutic device for determining hemodynamic parameters during hemotherapy comprising the step of determining a value of blood flow from the stored sequence of value pairs of the physical or chemical characteristic quantity  $X_A$  of the blood in the arterial branch of the extracorporeal circuit and of extracorporeal blood flow  $Q_B$ , at which value, after it is exceeded, the amount of the change in the physical or chemical interval is greater than a predetermined limiting value. See, e.g., col. 3, lines 9-33. Krämer, however, also fails to teach “inducing a disturbance in the blood flowing in the return line, said disturbance coming from a succession of increases and decreases of a value of a blood parameter around an average value or around a predetermined profile,” as recited in new claim 13, for example. Nor does Krämer disclose a method comprising the step of “determining a blood recirculation value in a vascular access of the patient between the return line and the withdrawal line, as a function of said at least first and second acquired values,”

relating to at least first and second variations of the blood parameter, as recited in new claim 19, for example.

In light of the above-described deficiencies of Bellco, Cavicchioli, and Krämer, Applicants respectfully submit that new claims 13, 19, 24, 28, 34, 38, and 42 are allowable over the applied reference. Moreover, claims 14-18, 20-23, 25-57, 35-37, 39-41, and 43 are allowable at least due to their dependence from allowable claims 13, 19, 24, 28, 34, 38, and 42, respectively.

Applicants respectfully traverse the Examiner's rejection of originally-filed claims 2-6 and 8-12, under 35 U.S.C. § 103(a) as obvious over Krämer. To the extent the Examiner's rejection under 35 U.S.C. § 103(a) is understood, Applicants note that in order to establish a *prima facie* case of obviousness, three basic criteria must be met. First, the prior art reference must teach or suggest all the claim elements. Second, there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify a reference. Third, there must be a reasonable expectation of success for the proposed modification of the teachings. See M.P.E.P. § 2143.

In rejecting originally-filed claims 2-6 and 8-12, the Examiner alleges that "Kramer inherently teaches taking multiple measurements of a blood parameter, which inherently includes at least one or a succession of variations of hemoglobin concentration as said parameter." Office Action at 7. The Examiner concludes, without citation to Krämer, or any other reference for that matter that, "it would have been obvious to one having ordinary skill in the art to choose to make measurements of

hemoglobin concentration variation to be used in the calculation as the desired parameter based on the design of a patient's treatment." *Id.*

Applicants respectfully submit that such unsupported assertions are insufficient to maintain the rejections to originally-filed claims 2-6 and 8-12 under 35 U.S.C. § 103(a). "The mere fact that [one of skill] in the art could rearrange the parts of the reference device to meet the terms of the claims...is not by itself sufficient to support a finding of obviousness. The prior art must provide a motivation or reason...to make the necessary changes in the reference device." *Ex parte Chicago Rawhide Mfg. Co.*, 223 USPQ 351, 353 (Bd. Pat. App. & Inter. 1984); MPEP § 2143.01.

In any event, even if Krämer were modifiable in the manner proposed by the Examiner (and Applicants do not agree that it is), Applicants respectfully submit that, for reasons discussed above, the reference would still fail to teach each and every element of new claims 13, 19, 24, 28, 34, 38, and 42 as required under MPEP § 2143.03. New claims 13, 19, 24, 28, 34, 38, and 42 are therefore allowable over Krämer for this reason also.

Further, as noted above, claims 14-18, 20-23, 25-57, 35-37, 39-41, and 43 are allowable at least due to their dependence from allowable claims 13, 19, 24, 28, 34, 38, and 42, respectively.

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

The Office Action contains characterizations of the claims and the related art, with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.


If the Examiner believes a telephone conversation might advance prosecution, the Examiner is invited to call Applicants' undersigned attorney at 202-408-4387.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account no. 06-0916.

Respectfully submitted,

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### **Attachments: Replacement Abstract**

A method is described for determining recirculation of blood in a vascular access of a patient undergoing dialysis treatment using a dialysis machine with an arterial line for withdrawing blood from the patient's body, a dialysis filter, and a venous line for returning blood to the patient's body. The method induces a disturbance in the blood flowing in the venous line. The disturbance is of a magnitude capable of bringing the system into a transient state and determining blood recirculation in the vascular access during the transient state as a function of the magnitude of the disturbance induced in the arterial line. In particular, the disturbance relates to the variation of the hemoglobin concentration in the blood flowing in the venous line. The variation is caused by controlling a change in the ultrafiltration flow in the dialysis filter.